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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/194,053

11/23/1998

MOHAMED CHOKRI

USB96AKIDM

2743

466

7590

05/24/2006

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EXAMINER

EWOLDT, GERALD R

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 05/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/194,053

Applicant(s)

CHOKRI ET AL.

Examiner

G. R. Ewoldt, Ph.D.

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1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 February 2006 and 20 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 44, 49, 50 and 91-104 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 44, 49, 50, and 91-104 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                        |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____   |

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#### DETAILED ACTION

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed 3/20/06 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendment and remarks, filed 2/09/06, have been entered.

2. Claims 44, 49, 50, and 91-104 are pending.

3. In view of Applicant's instant amendments and remarks the previous rejections under the second paragraph of 35 U.S.C. 112 have been withdrawn.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 44, 49, 50, and 91-104, stand/are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record as set forth in the paper mailed 7/29/02 and maintained in the papers mailed 5/07/03, 8/02/04, and 5/20/05.

As set forth previously, the instant invention is drawn to a previously undescribed type of antigen presenting cell that possesses properties of both macrophages, i.e., phagocytic capacity, and dendritic cells, i.e., superior antigen presentation. Given the unexpected nature of the cell of the instant claims, said cell must be considered highly unpredictable. As such, an enabling specification would require significant guidance and direction, and/or working examples. The specification, however, fails to adequately disclose to one of skill in the art how to make the invention of the instant claims as broadly claimed, or even that the MD-APCs of the instant claims indeed exist as a single, specific, cell type.

The specification discloses that the MD-APCs of the instant claims are produced by a method of culturing monocytes in a medium comprising GM-CSF, cimetidine, and

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histamine and are characterized as being positive for surface antigens CD14, CD64, CD80 and CD86, and devoid of surface antigens CD1a, CD1c and CD83, as determined by immunofluorescence staining and flow cytometry analysis. It is noted that the specification discloses no immunofluorescence staining and flow cytometry analysis data, but merely discloses Applicant's analysis of uncontrolled data as set forth in Tables 1-5. It is the Examiner's position that the cells of the instant claims are much more likely to comprise a mixed cell culture of dendritic cells and macrophages than they are to comprise a single new, and previously undescribed, cell type. This is the Examiner's position particularly in view of the disclosure at page 5 that only 10% of the claimed cells need express CD14, only 10% of the claimed cells need express CD64, only 30% of the claimed cells need express CD80, and only 30% of the claimed cells need express CD86, a description that most certainly describes a mixed cell population.

Applicant has provided no additional arguments in traversal of this rejection.

6. Claims 44, 49, 50, and 91-104 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

As set forth previously, The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) Monocyte-derived antigen-presenting cells (MD-APCS) having been produced by differentiating blood monocytes in vitro, in the presence of lymphocytes, GM-CSF and at least one ligand having a receptor on the surface of monocytes, said MD-APCS having, when compared with monocyte derived macrophages prepared in the presence of GM-CSF only, higher phagocytic properties of formalin fixed yeast and higher ability for stimulation of allogenic T lymphocytes, in Claims 44, 97, and 104.

Applicant argues that in view of the instant amendment wherein the phrase "higher phagocytic properties of formalin fixed yeast" has been deleted the rejection has been overcome.

While the amendment removes a portion of the new matter, the phrase "higher ability for stimulation of allogenic T lymphocytes" remains.

7. Claims 91-104 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at

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the time the application was filed. This is a new matter rejection.

As set forth previously, The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

All of the limitations of Claims 91-104.

Applicant has not indicated where any support for any of the limitations of the new claims can be found. Applicant has merely stated that support can be found in the original claims and generally throughout the specification.

Upon careful review of the specification no support has been found for the specific combinations of limitations that have been cobbled together in the newly added claims. Some of the limitations, e.g., wherein the MD-APC comprises a surface receptor for the ligand IL-13 (Claim 13) is not found at all (IL-13 is disclosed only in combination with GM-CSF, page 14) are not disclosed at all. Others, e.g., culture in hydrophobic bags (Claims 93 and 101) are broader than the disclosure (only ethylene vinyl acetate and polypropylene hydrophobic bags are disclosed, and then only in specific examples, page 10). Still other claims recite limitations found in one specific example in combination with limitations found in other examples, or in the generic disclosure e.g., the example at page 7 (absent the 5 to 15 days of culture) incorporating the concentrations of reagents set forth at page 6 (Claim 94). Finally, in Claim 104, the cell of the claim is described by the recitation of selected cell surface markers, CD14, CD64, CD80, and CD86, while other cell surface markers, e.g., HLA-DR are ignored. The specification fails to describe the claimed cells in this selective manner, see for example, Table 2.

Applicant has provided no arguments in traversal of these rejection.

8. The following are new grounds of rejection.

9. Claims 44, 49, 50, and 91-104 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

the phrase "...such that at least about 60% of a population of said MD-APCS exhibit an update of formalin-fixed yeast after culturing said MD-APCS for 3 hours..." in Claims 44, 97 and 104 is not supported by the specification in the context in which it is now recited.

Applicant cites page 18, lines 19-24 in support.

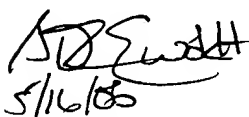
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A review of the specification shows that the cite at page 18, lines 19-24 discloses only the results of a specific experiment wherein specific concentrations of histamine and cimetidine were employed. The cite does not support the generic limitation of the instant claims.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

12. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Inquiries of a general nature may also be directed to the Technology Center 1600 Receptionist at (571) 272-1600.



5/16/05

G.R. Ewoldt, Ph.D.  
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Technology Center 1600